TRULY® Truly Instrument Limited K113085

510(k) Summary

JAN 1 2 2012

Date of Summary Preparation: August.16.2011

1. Submitter's Identifications

Submitter's Name:	Truly Instrument Limited
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2. Name of the Device

Device Classification Name: System, Measurement, Blood-Pressure, Non-invasive

Trade Nam:	Truly Automatic Wrist Blood Pressure Monitor
Models:	DW801, DW802, DW803, DW805, DW806, DW807, DW808, DW901, DW902, DW903
Classification Panel:	cardio-vascular
Common/Usual Name:	Automatic Wrist Blood Pressure Monitor
Product Code:	DXN
Device Classification:	Class II
Contraindications :	N/A

3. The Predicate Devices

Truly Automatic Wrist Blood Pressure Monitor, Model DW700, K091415

4. Device Description

Truly Automatic Wrist Blood Pressure Monitor DW series, Models DW801, DW802, DW803, DW805, DW806, DW807, DW808, DW901, DW902, DW903 are designed to measure the systolic and diastolic blood pressure and pulse rate of an individual by using a non-invasive technique in which an inflatable cuff is wrapped around the wrist. Our method to define systolic and diastolic pressure is similar to the auscultatory method but uses an electronic pressure sensor rather than a stethoscope and mercury manometer. The sensor converts tiny alterations in cuff pressure to electrical signals, by analyzing those signals to define the systolic and diastolic blood pressure and calculating pulse rate, which is a well-known technique in the market called the "oscillometric method".

The main components of the Truly Automatic Wrist Blood Pressure Monitor DW series are the main unit and cuff unit. ABS is used to outer housing of the main unit. The preformed cuff unit, which is applicable to arm circumference approximately between 135 and 220 mm, includes the inflatable bladder and nylon shell. All models of the wrist blood pressure monitor use a single size of cuff. The device consists of the microprocessor, the pressure sensor, the operation keys, the pump, the electromagnetic deflation control valve and the LCD. The subject devices are powered by two AAA alkaline batteries.

The device also compares the longest and the shortest time intervals of detected pulse waves

to mean time interval and displays a warning signal with the reading to indicate the detection of irregular pulse rhythm when the difference of the time intervals is over 25%.

5. Intended use of device

Truly Automatic Wrist Blood Pressure Monitor DW series, Models DW801, DW802, DW803, DW805, DW806, DW807, DW808, DW901, DW902, DW903 are a series devices intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the wrist.

The devices features include irregular pulse rhythm detection during measurement, and display a warning signal with the reading once the irregular heartbeat is detected.

6. Summary of Substantial Equivalence

Table-1: The comparison table

Parameter	Predicate Device DW700	DW 801	DW 802	DW 803	DW 805	DW 806	DW 807	DW 808	DW 901	DW 902	DW 903	Result
Intended use	Measuring systolic and diastolic blood pressure and pulse rate of adult individual	Measuring systolic and diastolic blood pressure and pulse rate of adult individual										Same
Indications for use	Measuring systolic and diastolic blood pressure and pulse rate of adult individual, Including irregular pulse rhythm detection . Over-The-Counter Use	Measuring systolic and diastolic blood pressure and pulse rate of adult individual, Including irregular pulse rhythm detection . Over-The-Counter Use										Same
Target Population	Adult	Adult										Same
Anatomical sites	Wrist	Wrist										Same
Where used (hospital, home, ambulance. etc)	Home	Home										Same
Energy used and / or delivered	2x 1.5V AAA Battery	2x 1.5V AAA Battery										Same
Human factors	Blood pressure	Blood pressure										Same
design	Refer to Table-2											Same
performance	Measuring systolic and diastolic blood pressure and pulse rate of adult individual, Including irregular pulse rhythm detection	Measuring systolic and diastolic blood pressure and pulse rate of adult individual, Including irregular pulse rhythm detection										Same
materials	Refer to Table-2											Same
biocompatibility	Cuff According to ISO-10993	Cuff According to ISO-10993										Same
Compatibility with the environment and other devices	Operation Environment: 10℃~ 40℃, 15%~90%RH Storage Environment:	Operation Environment: 10℃~ 40℃, 15%~90%RH Storage Environment:										Same

Parameter	Predicate Device DW700	DW 801	DW 802	DW 803	DW 805	DW 806	DW 807	DW 808	DW 901	DW 902	DW 903	Result
	-20℃~ 60℃, 10%~95%RH	-20℃~ 60℃, 10%~95%RH										
sterility	N/A	N/A										Same
Electrical safety	According to IEC60601-1-2 According to IEC60601-1	According to IEC60601-1-2 According to IEC60601-1										Same
Mechanical safety	Same	Same										Same
Chemical safety	N/A	N/A										Same
Thermal safety	N/A	N/A										Same

Table-2: The comparison table in Design and Materials

Parameter	Predicate Device DW700	DW 801	DW 802	DW 803	DW 805	DW 806	DW 807	DW 808	DW 901	DW 902	DW 903	
Measurement algorithm Method	Oscillometric method	No change ,all same										
Measurement site of body	Wrist	No change ,all same										
Pressure Sensor	MSP-2107	No change ,all same										
Cuff		No change ,all same										
Software		No change ,all same										
Irregular heartbeat detection		More than ±25% to the mean interval of pulse intervals. About the more detailed description of the IH detection algorithm, please refer to "Software validation report I-5. Algorithm description 4. Determination method of irregular heartbeat"..										
Memory Size												
Measurement Pressure Range	20 ~ 280 mmHg	No change ,all same										
Measurement Pulse Range	40 ~ 195 beats/min	No change ,all same										

Parameter	Predicate Device DW700	DW 801	DW 802	DW 803	DW 805	DW 806	DW 807	DW 808	DW 901	DW 902	DW 903
Mesauring resolution	1 mmHg	No change ,all same									
Accuracy Pressure	±3mmHg	No change ,all same									
Accuracy Pulse	±5%	No change ,all same									
Pressurization Source	Automatic internal pump	No change ,all same									
Cuff Deflation	Automatic deflation	No change ,all same									
Operating Environment	10~40℃ 15~90%RH	No change ,all same									
Power Voltage	2 x 1.5V	No change ,all same									
Hardware circuit		No change ,all same									
Electronic element		No change ,all same									
PCB		No change ,all same									
Display Type	Liquid crystal display	Liquid crystal display ,Only difference size									
Cover		Difference									

7. Summary of Clinical study

1). Subjects:

Ninety subjects including 15 hypertensive patients in the hospital were participated in clinical study.

2). Method:

A standard mercury sphygmomanometer was used as a reference standard. Simultaneous and blinded blood pressure determinations were performed by two doctors.

3). Criteria:

The ANSI/AAMI SP10 Standard recommended :

A. a mean difference of x5mmHg, with standard deviation of differences of x8 mmHg between test device and reference method.

B. Between-observer agreement should be:95% or more of readings made simultaneously by observers agree to within x10mmHg and 85% or more agree to within x5 mmHg.

4). Result

Through clinical research, we can convinced that the clinical device is safe and effective. The results of the clinical data refer the follow two tables.

Table-1 Between test device and reference method

Criteria		Test Result	
		Systolic Pressure	Diastolic Pressure
Mean differences	x 5 mmHg	-3.5 mmHg	-3.2 mmHg
SD differences	x 8 mmHg	3.5 mmHg	3.5 mmHg

Table-2 Betwee-observer agreement

Criteria	Test Result	
	Systolic Pressure	Diastolic Pressure
At least 95% of readings agree to within x 10mmHg	100%	100%
At least 85% of readings agree to within x 5mmHg	99%	99%

6. Conclusions

The new subject series devices of Truly Automatic Wrist Blood Pressure Monitor continue to follow principles of hardware and software design of the predicate device DW700(K091415), and the feature, safety, effectiveness are also as same as Dw700., just only in case and LCD''s size changes. Thus, the subject devices are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JAN 12 2012

Truly Instrument Co., Ltd.
c/o Mr. Yang Jian-Hao
Manager
Site 2, Truly Industry Area
Shan Wei, Guang Dong 516600
China

Re: K113085
Trade/Device Name: Truly Automatic Wrist Blood Pressure Monitor Models DW801, DW802, DW803, DW805, DW806, DW807, DW808, DW901, DW902, DW903
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: August 16, 2011
Received: October 18, 2011

Dear Mr. Yang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(K) Number (if Known) K113085

Device Name: Truly Automatic Wrist Blood Pressure Monitor DB Series:

Models DW801, DW802, DW803, DW805, DW806, DW807, DW808, DW901, DW902, DW903

Indication For Use:

Truly Automatic Wrist Blood Pressure Monitor, Models DW801, DW802, DW803, DW805, DW806, DW807, DW808, DW901, DW902, DW903 are a series device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the wrist.

The devices features include irregular pulse rhythm detection during measurement, and display a warning signal with the reading once the irregular heartbeat is detected.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K113085